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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,197	11/27/2000	Kathleen E. Rodgers	97,017-P7	4161

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

10

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/723,197

Applicant(s)

RODGERS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,7-10,14 and 19-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-10,14 and 19-29 is/are rejected.
- 7) ☒ Claim(s) 30-47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 7-10, 14 and 19-47 are pending.

Applicant's amendment filed on November 26, 2002 (Paper No. 9) is acknowledged.

Applicants' response has been fully considered. Claims 2-6, 11-13 and 15-18 have been cancelled, claims 1, 7-10, 14, 20 21, 28 and 29 have been amended, and new claims 35-47 have been added. Thus, claims 1, 7-10, 14 and 19-47, and SEQ ID NO:4 are examined.

### **Objection Withdrawn**

2. The previous objection to the specification regarding using the brackets [...] in the text is withdrawn in view of applicants' amendment to the specification and applicants' response at page 6 in Paper No. 9.

### **Rejection Withdrawn**

#### ***Claim Rejections-Obviousness Type Double Patenting***

3. The previous rejection of claims 2-6, 11-13 and 15-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 7, 25, 26, 28, 31-33, 35-38, 41-43 and 46-48 of copending application No. 09/307,940, is withdrawn in view of applicants' cancellation of the claim in Paper No. 9.

#### ***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 1-34 under 35 USC § 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at pages 7-9 in Paper No. 9.

### ***Claim Objections***

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5. Claims 1, 7-10, 19-28 and 30-47 are objected to because the claim contains non-elected sequences, e.g., the amino acid sequence of formula I contains D-Arg as R<sup>2</sup>, Leu or NorLeu as R<sup>2</sup>. As indicated in the restriction requirement, the sequence election is not a species election, each peptide with different amino acid sequence is patentably distinct.

***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 7-10, 14 and 19-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of Patent 6,475,988 (issued at November 5, 2002; the copending application No. 09/307,940). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 7-10, 14 and 19-29 in the instant application disclose an improved method for chemotherapy in a human patient, comprising administering an effective amount of an active agent comprising a sequence of formula I (R<sup>1</sup>-R<sup>2</sup>-R<sup>3</sup>-R<sup>4</sup>-R<sup>5</sup>-R<sup>6</sup>-R<sup>7</sup>-R<sup>8</sup>) which includes SEQ ID NO:4 for treating or preventing chemotherapy side effects; and a pharmaceutical composition comprising the active agent and a pharmaceutically acceptable carrier. This is obvious in view of claims 1-18 of the patent which discloses a method for increasing white blood cell survival

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following chemotherapy comprising administering an effective amount of an active agent comprising a sequence of Asp-Arg-R1-R2-Ile-His-Pro-R3 (SEQ ID NO:42) or formula I ( $R^1-R^2-R^3-R^4-R^5-R^6-R^7-R^8$ ) which includes SEQ ID NO:4; and a pharmaceutical composition comprising the active agent, a cytotoxic agent and a pharmaceutically acceptable carrier, where the limitations are also cited in the instant application. Thus, claims 1, 7-10, 14 and 19-29 in present application and claims 1-18 of the patent are obvious variations of a method for treating chemotherapy side effects in a patient comprising administering an effective amount of an active agent comprising a sequence of formula I ( $R^1-R^2-R^3-R^4-R^5-R^6-R^7-R^8$ ) which includes SEQ ID NO:4, and a pharmaceutical composition comprising the active agent.

#### ***Conclusion***

8. Claims 1, 7-10, 14 and 19-29 are rejected, and claims 30-47 are objected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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February 18, 2003

*Karen Cochrane Carlson PhD*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER